FEB 17 1999

NDA 9-175/S-020

Dura Pharmaceuticals
Attention: Terry L. Monk
Labeling Compliance Administrator
7475 Lusk Boulevard
San Diego, CA 92121

Dear Ms. Monk:

Please refer to your supplemental new drug application dated December 7, 1992, received December 8, 1992, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FURADANTIN (nitrofurantoin) Oral Suspension.

We acknowledge receipt of your submissions dated February 26,1993, December 20, 1995, May 8,1998, and November 6,1998.

This supplemental new drug application provides for revisions to the **WARNINGS** and **ADVERSE REACTIONS** sections of the labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 6, 1998). Accordingly, the supplemental application is approved effective on the date of this letter.

However, in the approval letter for S-020 dated April 7, 1998, the FDA requested that the following sentences be moved from the **Laboratory Events** subsection to the **Allergic** subsection of the **ADVERSE REACTIONS** section of the labeling and replaced by the single sentence "Hypersensitivity reactions present the most frequent spontaneously-reported adverse events in worldwide postmarketing experience with nitrofurantoin formulations.":

"Hypersensitivity reactions present the most frequent spontaneously-reported adverse events in worldwide postmarketing experience with nitrofurantoin formulations. In almost all cases, the events are reversible after discontinuation of the drug."

While you did add the former sentence to the **Allergic** subsection, you did not remove the two sentences from the **Laboratory Events** subsection. Therefore, at the time of the next printing, please remove the two sentences noted above from the **Laboratory Events** subsection of the **ADVERSE REACTIONS** section of the labeling.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research